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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,385	04/25/2002	Silvia Buervenich	1103326-0677	1420

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WHITE & CASE LLP
PATENT DEPARTMENT
1155 AVENUE OF THE AMERICAS
NEW YORK, NY 10036

EXAMINER

QIAN, CELINE X

ART UNIT	PAPER NUMBER
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1636

MAIL DATE	DELIVERY MODE
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10/25/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/019,385	Applicant(s) BUERVENICH ET AL.	
	Examiner Celine X. Qian Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-20 and 24-37 is/are pending in the application.
- 4a) Of the above claim(s) 12-20,24-31 and 35-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-11 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1-6, 8-20, 24-37 are pending in the application. Claim 12-20, 24-31, 35-37 are withdrawn from consideration. Claims 1-6, 8-11, 32-34 are currently under examination.

This Office Action is in response to the Amendment filed on 8/16/07.

Response to Amendment

The amendment to the specification is entered.

The rejection of claim 7 under 102 (b) is moot because the claim has been canceled.

The rejection of claims 1, 3-6, 8-11, 34 under 35 U.S.C.112 2nd paragraph has been withdrawn in light of Applicant's amendment.

The rejection of claim 9 under 35 U.S.C.101 has been withdrawn in light of Applicant's amendment.

The rejection of claim 33 under 35 U.S.C.101 is maintained for reasons set forth of the record mailed on 5/16/07 and further discussed below.

The rejection of claims 1-6, 8-11, 32-34 under 35 U.S.C. 112 1st paragraph is maintained for reasons set forth of the record mailed on 5/16/07 and further discussed below.

Claims 32 and 33 are rejected under 35 U.S.C.112 2nd paragraph for reason discussed below.

Response to Arguments

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claim 33 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

In response to this rejection, Applicants assert that the claim has been amended as suggested by the examiner. However, a review of claim 33 reveals that no amendment has been made to this claim. Therefore, claim 33 is rejected for same reason as stated in the previous office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 8-11, 32-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In response to this rejection, Applicants argue that the assessment of the claims are not complete because the claimed genus must also have the same function, and the breadth of the claim is narrower than the examiner's assessment. Applicants further assert that the specification teaches the invention have all four mutations although deletion of 121 and 122 are indistinguishable. Applicants assert that the two deletions must be considered as separate aspects of the invention. Furthermore, Applicants assert that the invention do not encompass sequences unrelated to Nurrl gene because the sequences are derived from the parent Nurrl gene.

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Moreover, Applicants assert that the four mutations are conserved in other species as evidenced by the disclosure of US 7,037,657. Lastly, Applicants assert that since Nurr1 gene is conserved among many species, the skilled artisan would have reasonable expectation that the mutations of the present invention would exert the same effects on species other than human.

The above arguments have been fully considered but deemed unpersuasive. The reason for lack adequate description of the claimed genus of the nucleic acid was discussed in the previous office action. In response to Applicant's arguments, Applicants are reminded that the claims do not include functional limitation of the claimed Nurr1 gene, fragments or variants. In fact, the whole point of the rejection is that the structural and functional relationship between the claimed genus of the nucleic acid and their function is missing. As for the function of the Nurr1 gene, the specification discloses that it can bind to NurRE and direct transcription, wherein the three mutations in exon 3 results in the impairment of its function. It is also know that Nurr1 can form homodimer. As such, when referring to the fragments and variants that have same function, it is unclear what is the unifying function that all those fragments and variants must share. Without a functional limitation, the claimed nucleic acid can only be identified by its structural limitation, that is nucleic acids encoding a protein that has the recited mutation, and it would have encompasses fragments and variants that encodes protein have different function because comprising a mutation at the recited position does not indicate any function. As for the argument of all the sequences are derived from Nurr1, it is unclear what sequence these fragments or variants must have to be considered as a derivative of the parent gene. The instant specification does not describe any such claimed fragments or variants. Even the Nurr1 is conserved in many species, the claimed invention does not have adequate support for the

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fragments and variants because the specification fails to describe the claimed genus by a representative number of species by its complete structure or other identifying characteristics. Therefore, for reasons discussed in the previous office action and above, this rejection is maintained.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 depends on claim 7, which is canceled by the amendment filed on 8/16/07. As such, it is unclear what is the limitation included in this claim. Claim 33 is also rejected because it depends on claim 32.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 12-20, 24-31, 35-37 drawn to an invention nonelected with traverse in the response filed on 2/14/07. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER

